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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/780,963

Applicant(s)

LAU ET AL.

Examiner

Angela M. Bertagna

Art Unit

1637

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74, 76-84, 86 and 87 is/are pending in the application.
- 4a) Of the above claim(s) 1-20, 25-44 and 50-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-24, 45-49, 66-74, 76-84, 86 and 87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

1. Applicant's response filed on September 30, 2009 is acknowledged. Claims 1-74, 76-84, 86, and 87 are currently pending. Claims 1-20, 25-44, and 50-65 remain withdrawn from consideration as being drawn to a non-elected invention. Applicant's arguments filed on September 30, 2009 and the supplemental declaration filed under 37 CFR 1.131 have been fully considered, but they were insufficient to overcome the previously made rejections for the reasons set forth below. Accordingly, this Office Action is made **FINAL**.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 21, 22, 24, 45, 46, 48, 49, 66-69, and 76-79 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Hennessy et al. (US 2004/0016702 A2; cited previously).

These claims are drawn to methods of purifying PCR and DNA sequencing products using particles comprising a core for ion exchange and a polyelectrolyte coating comprising at least one charged monomer and at least one neutral co-monomer.

Regarding claims 21 and 45, Hennessy teaches a method for purifying PCR reaction products or DNA sequencing reaction products, comprising:

(a) providing a plurality of particles, wherein each particle comprises an ion-exchange core coated by exposing the core to a polyelectrolyte copolymer comprising at least one type of charged monomer and at least one type of neutral co-monomer (see paragraphs 25-29, 36, 37, and 68)

(b) providing a mixture of cationic ion-exchange particles and anionic ion-exchange particles, wherein the plurality of particles are either the cationic ion-exchange particles or the anionic ion-exchange particles (paragraph 26, 37, 60, and 77)

(c) contacting the PCR reaction products or DNA sequencing reaction products with the plurality of particles of step (a) to separate and purify the dsDNA fragments or dye-labeled ssDNA fragments, respectively (see paragraphs 28, 29, 36, 47, 62, 70, 71, 79, and 80).

Regarding claims 22 and 46, Hennessy teaches that the contacting comprises moving the PCR reaction products or the DNA sequencing reaction products through the particles using centripetal force (paragraph 29, where spin columns are taught).

Regarding claim 24, Hennessy teaches that the method of claim 21 further comprises positioning a mixture comprising the plurality of particles in a column (see paragraphs 26-29).

Regarding claim 48, Hennessy teaches that the method of claim 45 further comprises removing residual dye artifacts (paragraphs 36, 71, and 80).

Regarding claim 49, Hennessy teaches that the method of claim 45 further comprises maintaining dye-labeled ssDNA fragment length (paragraphs 36, 71, and 80).

Regarding claims 66 and 76, Hennessy teaches coupling of the ion-exchange core with a PCR reaction product, such as dNTPs or primers (paragraph 79) or a DNA sequencing reaction product, such as dye-labeled nucleotides or salts (paragraphs 71 and 80).

Regarding claims 67 and 77, Hennessy teaches that the particle is adapted to substantially exclude dsDNA fragments having greater than 100 basepairs (paragraph 79) or ssDNA fragments greater than 45 nucleotides in length (paragraph 71).

Regarding claims 68 and 78, Hennessy teaches that the core comprises porous ion-exchange material (paragraphs 73-75).

Regarding claims 69 and 79, Hennessy teaches that the ion-exchange material is surface-activated (paragraphs 40 and 73).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 23, 47, 70-72, 80-82, 86, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hennessy et al. (US 2004/0016702 A2; cited previously).

Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as Hennessy at the time this invention was made, or was subject to a joint research agreement at the time this invention was made. However, the Hennessy reference additionally qualifies as prior art under another subsection of 35 U.S.C. 102, specifically 102(a), and therefore, is not disqualified as prior art under 35 U.S.C. 103(c).

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CFR 1.131.

Claim 23 is drawn to the method of claims 21, wherein the plurality of particles comprise a first volume and the PCR products comprise a second volume that is less than or equal to the first volume. Claim 47 is drawn to the method of claim 45, respectively, wherein the plurality of particles comprise a first volume and the DNA sequencing reaction products comprise a second volume that is greater than or equal to the volume of the plurality of particles. Claims 70-72 and 80-82 further limit the pore size of the ion-exchange material and the molecular weight of the polyelectrolyte copolymer material. Claims 86 and 87 recite that the polyelectrolyte copolymer is present in the particles within a given range of concentrations.

Hennessy teaches the method of claims 21, 22, 24, 45, 46, 48, 49, 66-69, and 76-79, as discussed above.

Regarding claims 23 and 47, Hennessy does not specify volumes at which the particles, DNA sequencing products, or the PCR products should be used

Regarding claims 70-72 and 80-82, Hennessy teaches that the ion-exchange material has a pore size less than or equal to 1000 Angstroms, from 100 Angstroms to 1000 Angstroms, or less than or equal to 100 Angstroms (paragraph 73). These ranges overlap with the claimed range of 100 Angstroms to 2000 Angstroms (claim 70), 5 Angstroms to 1000 Angstroms (claim 80), and 10 Angstroms to 50 Angstroms (claim 82).

Hennessy does not teach specific molecular weights for the polyelectrolyte copolymer material as required by claims 71, 72, 81, and 82. Hennessy also does not teach the molar percentage of the charged monomer in the polyelectrolyte copolymer material as required by claims 86 and 87.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to optimize the following results-effective variables when practicing the method taught by Hennessy: (1) the volume of the particles, PCR products, and DNA sequencing products, (2) the pore size of the ion-exchange material, (3) the molecular weight of the polyelectrolyte copolymer material, and (4) the molar percentage of the charged monomer in the polyelectrolyte copolymer material. An ordinary artisan would have recognized that optimization of these results-effective variables was critical for successful practice of the method taught by Hennessy, and therefore, would have been motivated to optimize the aforementioned results-effective variables using routine experimentation with a reasonable expectation of success. As noted in

MPEP 2144.05, optimization of results-effective variables using routine experimentation is *prima facie* obvious in the absence of unexpected results. In this case, there is no evidence to suggest that the selection of the claimed volumes, pore sizes, molecular weights, or molar percentages was other than routine or that the results should be considered unexpected compared to the prior art of Hennessy. Thus, the methods of claims 23, 47, 70-72, 80-82, 86, and 87 are *prima facie* obvious over Hennessy in the absence of secondary considerations.

6. Claims 73, 74, 83, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hennessy et al. (US 2004/0016702 A2; cited previously) in view of Breadmore et al. (WO 03/104774 A1; cited previously).

Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as Hennessy at the time this invention was made, or was subject to a joint research agreement at the time this invention was made. However, the Hennessy reference additionally qualifies as prior art under another subsection of 35 U.S.C. 102, specifically 102(a), and therefore, is not disqualified as prior art under 35 U.S.C. 103(c).

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CFR 1.131.

Claims 73, 74, 83, and 84 are drawn to the methods of claims 21 and 45, further wherein the polyelectrolyte coating comprises polyanions and polycations added in alternating layers.

Hennessy teaches the method of claims 21, 22, 24, 45, 46, 48, 49, 66-69, and 76-79, as discussed above.

Hennessy does not teach that the polyelectrolyte coating is comprised of alternating layers of polyanions and polycations.

Breadmore teaches a method of nucleic acid purification using silica-based extraction procedures (see pages 1-2 for a general description). Regarding claims 73, 74, 83, and 84, Breadmore teaches increasing the yield of the purification method by modifying the silica surface with polyelectrolytes. Specifically, Breadmore teaches that the stability of the adsorbed polyelectrolyte layer can be improved by using multiple layers. Breadmore further teaches coating the silica particles with a cationic polymer followed by a second coating with an anionic polymer and repeating this process to form a multilayer (see page 13).

It would have been *prima facie* obvious for one of ordinary skill in the art to coat the particles taught by Hennessy with multiple alternating layers of polycations and polyanions, since Breadmore taught that such treatment improved the stability of the adsorbed polyelectrolyte layer (see page 13, cited above). Breadmore also taught that such modifications of silica-based resins improved purification yields (see page 13), thereby providing additional motivation for an ordinary artisan to coat the particles taught by Hennessy with multiple alternating layers of polycations and polyanions. Since the resins taught by Breadmore were used for purification of nucleic acids, including PCR and DNA sequencing reaction products (page 2, lines 1-4), an ordinary artisan would have expected a reasonable level of success in using the resulting particles coated with multiple alternating layers of polyelectrolytes in the

method taught by Hennessy. Thus, the methods of claims 73, 74, 83, and 84 are *prima facie* obvious over Hennessy in view of Breadmore.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 45, 80-82, and 87 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8, 21, and 29-36 of copending Application No. 11/057,936 in view Hennessy et al. (US 2004/0016702 A1; cited previously).

The instant claims 45, 80-82, and 87 are drawn to a method for purifying DNA sequencing reaction products using a plurality of particles having an ion-exchange core coated

with a polyelectrolyte copolymer comprising at least one charged monomer and at least one neutral co-monomer.

Claims 8, 21, 30, 31, 34, and 35 of the '936 application recite a method for DNA sequencing comprising contacting sequencing reaction products with particles comprising an ion exchange core coated with a polyelectrolyte copolymer comprising at least one positively or negatively charged monomer and at least one neutral co-monomer, isolating the particles, and sequencing the purified sequencing products. The claims of the '936 application recite all of the limitations of the instant claim 45 with the exception of providing a mixture of cationic and anionic ion exchange particles. Regarding the instant claims 80-82, claims 32 and 36 of the '936 application recite that the polyelectrolyte copolymer material has an average molecular weight of between about 1000 Da to about 6.0 MDa. This range overlaps with the instantly claimed ranges. The limitations of the instant claim 87 are recited in claims 29 and 33 of the '936 application.

It would have been *prima facie* obvious for one of ordinary skill in the art to provide a mixture of cationic and anionic ion-exchange particles when practicing the method recited in claims 8, 21, and 29-36 of the '936 application. An ordinary artisan would have been motivated to do so, because Hennessy taught that when a mixture of anionic and cationic ion exchange particles was used to purify a sample, the counterions of the anionic and cationic ion exchange particles reacted to form a neutral molecule, such as water, that did not affect down-stream processing of the sample (see paragraph 77). Based on these teachings of Hennessy, an ordinary artisan would have recognized that using a mixture of cationic and anionic ion exchange particles to purify DNA sequencing reaction products would have improved the purification method

recited in claims 8, 21, and 29-36 of the '936 application by neutralizing counterions released by the polyelectrolyte-coated anion exchange particles during the purification.

Also, regarding the instant claims 80-82, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to optimize the pore size of the ion-exchange material and the molecular weight of the polyelectrolyte copolymer material when practicing the method recited in claims 8, 21, and 29-36 of the '936 application. An ordinary artisan would have recognized that optimization of these results-effective variables was critical for successful practice of the method recited in claims 8, 21, and 29-36 of the '936 application, and therefore, would have been motivated to optimize the aforementioned results-effective variables using routine experimentation with a reasonable expectation of success. As noted in MPEP 2144.05, optimization of results-effective variables using routine experimentation is *prima facie* obvious in the absence of unexpected results. In this case, there is no evidence to suggest that the selection of the claimed volumes, pore sizes, molecular weights, or molar percentages was other than routine or that the results should be considered unexpected. Thus, the methods of claims 45, 80-82, and 87 are an obvious variant of the method recited in claims 8, 21, and 29-36 of copending application 11/057,936 in view of Hennessy in the absence of secondary considerations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 45, 80-82, and 87 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 15, 21, 22, and 28-35

of copending Application No. 11/355,872 in view of Hennessy et al. (US 2004/0016702 A1; cited previously).

The instant claims 45, 80-82, and 87 are drawn to a method for purifying DNA sequencing reaction products using a plurality of particles having an ion-exchange core coated with a polyelectrolyte copolymer comprising at least one charged monomer and at least one neutral co-monomer.

Claims 12, 15, 21, 22, 29, 30, 33, and 34 of the '872 application recite a method for DNA sequencing comprising contacting sequencing reaction products with particles comprising an ion exchange core and a coating of a polyelectrolyte copolymer comprising at least one charged monomer and at least one neutral co-monomer, isolating the particles, and sequencing the purified sequencing products. These claims of the '872 application recite all of the limitations of the instant claim 45 with the exception of providing a mixture of cationic and anionic ion exchange particles as required by the instant claim 45. Regarding the instant claims 80-82, claims 31 and 35 of the '872 application recite that the polyelectrolyte copolymer material has an average molecular weight of between about 1000 Da to about 6.0 MDa. This range overlaps with the instantly claimed ranges. The limitations of the instant claim 87 are recited in claims 28 and 32 of the '936 application.

It would have been *prima facie* obvious for one of ordinary skill in the art to provide a mixture of cationic and anionic ion-exchange particles when practicing the method recited in claims 12, 15, 21, 22, and 28-35 of the '872 application. An ordinary artisan would have been motivated to do so, because Hennessy taught that when a mixture of anionic and cationic ion exchange particles was used to purify a sample, the counterions of the anionic and cationic ion

exchange particles reacted to form a neutral molecule, such as water, that did not affect downstream processing of the sample (see paragraph 77). Based on these teachings of Hennessy, an ordinary artisan would have recognized that using a mixture of cationic and anionic ion exchange particles to purify DNA sequencing reaction products would have improved the purification method recited in claims 12, 15, 21, 22, and 28-35 of the '872 application by neutralizing counterions released by the polyelectrolyte-coated anion exchange particles during the purification.

Also, regarding the instant claims 80-82, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to optimize the pore size of the ion-exchange material and the molecular weight of the polyelectrolyte copolymer material when practicing the method recited in claims 12, 15, 21, 22, and 28-35 of the '872 application. An ordinary artisan would have recognized that optimization of these results-effective variables was critical for successful practice of the method recited in claims 12, 15, 21, 22, and 28-35 of the '872 application, and therefore, would have been motivated to optimize the aforementioned results-effective variables using routine experimentation with a reasonable expectation of success. As noted in MPEP 2144.05, optimization of results-effective variables using routine experimentation is *prima facie* obvious in the absence of unexpected results. In this case, there is no evidence to suggest that the selection of the claimed volumes, pore sizes, molecular weights, or molar percentages was other than routine or that the results should be considered unexpected. Thus, the methods of claims 45, 80-82, and 87 are an obvious variant of the method recited in claims 12, 15, 21, 22, and 28-35 of copending application 11/355,872 in view of Hennessy in the absence of secondary considerations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Amendment

10. The supplemental declaration filed on September 30, 2009, under 37 CFR 1.131 has been considered, but it is ineffective to overcome the Hennessy reference.

As an initial matter, it is noted that neither the declaration filed on September 30, 2009 nor the declaration filed on January 14, 2009 has been signed by all of the inventors named on the instant application. As noted in MPEP 715.04 I, a declaration under 37 CFR 1.131 may be submitted by either: (A) all inventors of the claimed subject matter; or (B) less than all named inventors where it is shown that less than all named inventors of an application invented the subject matter of the claim or claims under rejection. In this case, Applicant has not established that less than all of the named inventors invented the subject matter of the instant claims, and therefore, a declaration signed by only one of the inventors is not sufficient to overcome the previously made rejection citing the Hennessy reference.

The supplemental affidavit filed on September 30, 2009, under 37 CFR 1.131 is also insufficient to overcome the Hennessy reference, because the evidence submitted does not establish a conception of the invention prior to the effective date of the Hennessy reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897).

The evidence previously submitted on January 14, 2009 shows that particles having an ion-exchange core and a polyelectrolyte copolymer coating comprising a neutral monomer and a charged co-monomer were conceived and made by Applicant prior to the effective date of the Hennessy reference (see Exhibits 3-4 and the accompanying explanation in point 8 of the affidavit). The supplemental declaration submitted on September 30, 2009 contains a statement by Dr. Aldrich Lau, who is one of the inventors listed on the instant application, indicating that his work "in inventing the polyelectrolyte coated particles of the present application included consideration of their use for purifying PCR reaction products and sequencing reaction products according to the methods set forth in pending claims 21 and 45 of this application (see point 6 of the declaration)".

The evidence submitted on January 14, 2009 and the supplemental declaration filed on September 30, 2009 have been carefully considered, but the evidence contained in the two declarations is not sufficient to establish conception of the claimed methods. As discussed previously, the instant claims are drawn to a method of using a plurality of particles in a mixture of anion exchange and cation exchange particles, wherein either the anion exchange particles or the cation exchange particles have the polyelectrolyte copolymer coating, to purify PCR products or DNA sequencing reaction products (see independent claims 21 and 45). The evidence submitted on January 14, 2009 only describes the synthesis of the particles and does not describe any methods for using them, particularly methods requiring their use in a mixture of oppositely charged ion exchange particles for the purification of PCR or DNA sequencing reaction products. The supplemental declaration filed on September 30, 2009 provides no evidence other than a general statement by one of the named inventors to indicate that conception of the claimed

methods occurred prior to the effective date of the Hennessy reference. As noted in MPEP 715.07 I, "A general allegation that the invention was completed prior to the date of the reference is not sufficient. *Ex parte Saunders*, 1883 C.D. 23, 23 O.G. 1224 (Comm'r Pat. 1883). Similarly, a declaration by the inventor to the effect that his or her invention was conceived or reduced to practice prior to the reference date, without a statement of facts demonstrating the correctness of this conclusion, is insufficient to satisfy 37 CFR 1.131." In this case, the supplemental declaration only contains a general statement alleging that the claimed methods were conceived and reduced to practice prior to the effective date of the Hennessy reference. No evidence (*e.g.* laboratory records) has been submitted to support this allegation, since the laboratory records previously submitted on January 14, 2009 only describe synthesis of particles having the features recited in the claims and do not describe or suggest any methods for their use. Accordingly, the evidence submitted does not establish conception of the claimed methods prior to the effective date of the Hennessy reference.

The evidence submitted is also insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Hennessy reference. As discussed above, the instant claims are drawn to methods of using a plurality of particles having an ion exchange core and a polyelectrolyte copolymer coating in a mixture of anion exchange and cation exchange particles, wherein either the anion exchange particles or the cation exchange particles have the polyelectrolyte copolymer coating, to purify PCR products or DNA sequencing reaction products (see independent claims 21 and 45). The evidence submitted on January 14, 2009 only describes the synthesis of the particles and does not describe any methods for using them, particularly methods requiring their use in a mixture of

oppositely charged ion exchange particles for the purification of PCR or DNA sequencing reaction products. The supplemental declaration filed on September 30, 2009 only contains a general statement alleging that the claimed methods were conceived and reduced to practice prior to the effective date of the Hennessy reference. No evidence (*e.g.* laboratory records) has been submitted to support this allegation, since the laboratory records previously submitted on January 14, 2009 only describe synthesis of particles having the features recited in the claims and do not describe or suggest any methods for their use. As a result, the evidence submitted on January 14, 2009 and September 30, 2009 is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Hennessy reference.

Since the declaration filed under 37 CFR 1.131 is insufficient to overcome the Hennessy reference, the rejection of claims 21, 22, 24, 45, 46, 48, 49, 66-69, and 76-79 under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Hennessy has been maintained.

Response to Arguments

11. Applicant's arguments filed on January 14, 2009 have been fully considered, but they were not persuasive.

Regarding the rejection of claims 21, 22, 24, 45, 46, 48, 49, 66-69, and 76-79 made under 35 U.S.C. 102(a) and 102(e) as being anticipated by Hennessy, Applicant first argues that the declarations filed under 37 CFR 1.131 on January 14, 2009 and September 30, 2009 are sufficient to overcome the rejections based on the Hennessy reference (pages 2-3). Applicant initially argues that the declarations filed on January 14, 2009 and September 30, 2009 could be

considered to be atypical declarations made under 37 CFR 1.131, because they describe the differences between the particles of Hennessy and the particles of the instant invention in addition to antedating the Hennessy reference (see page 3).

Applicant's remarks regarding the formal requirements of the declarations are noted, but the declaration remains insufficient to overcome the rejections based on Hennessy. Regarding the differences between the claimed particles and those described by Hennessy, as discussed in greater detail below, the claim language continues to encompass the particles of Hennessy. Accordingly, the declaration is insufficient to demonstrate that the particles of Hennessy lie outside of the broadest reasonable interpretation of the claims that is consistent with the specification. The declaration is also insufficient as a declaration made under 37 CFR 1.131, because it has not been signed by all of the named inventors, and the evidence does not establish that less than all of the named inventors are the inventors of the claimed subject matter.

Applicant also argues that the previously submitted declaration by Dr. Aldrich Lau and the supplemental declaration establish conception and reduction to practice of the claimed methods prior to the effective date of the Hennessy reference (page 3). This argument was not persuasive, because the evidence submitted previously and on September 30, 2009 does not establish via evidence and not allegations that either conception or reduction to practice of the claimed methods occurred prior to the effective date of the Hennessy reference. As discussed above, the evidence submitted previously only describes the synthesis of the particles and does not describe any methods for using them. The previously submitted declaration and the supplemental declaration filed on September 30, 2009 do not offer any evidence other than a general statement by Dr. Lau to demonstrate that conception and/or a constructive or actual

reduction to practice occurred prior to the effective date of the Hennessy reference. As noted in MPEP 715.07 I, general allegations are not sufficient to establish conception or a reduction to practice in the absence of supporting evidence.

Applicant further notes that a declaration made under 37 CFR 1.131 need not show any more than the reference shows (page 3). Applicant's remarks are noted, but the fact remains that the evidence previously submitted and the supplemental declaration do not establish that conception and/or a constructive or actual reduction to practice occurred prior to the effective date of the Hennessy reference. In this case, the showing is not commensurate in scope with the claimed invention except for obvious differences, because the showing is only directed to a method for obtaining a particular product, whereas the claimed invention is drawn to methods for using the product to purify PCR or DNA sequencing reaction products.

Further regarding the rejection of claims 21, 22, 24, 45, 46, 48, 49, 66-69, and 76-79 made under 35 U.S.C. 102(a) and 102(e) as being anticipated by Hennessy, Applicant argues that Hennessy does not teach the requirement for "coating the ion-exchange core by exposing the ion-exchange core to a polyelectrolyte copolymer material" as recited in independent claims 21 and 45 (see pages 4-8). This argument was not persuasive, because the above recitation does not limit the claimed methods to those in which the polyelectrolyte copolymer material is preformed or prefabricated before it makes contact with the ion-exchange core particle as argued by Applicant. The above language only requires exposing the ion-exchange core particle to a polyelectrolyte copolymer to coat the ion-exchange core particle with a polyelectrolyte copolymer. Therefore, the claims do not exclude methods, such as those disclosed by Hennessy, in which the ion-exchange core particle is coated by a process comprising exposure of the ion-

exchange core particle to the polyelectrolyte copolymer as it is being formed by polymerization in the presence of the ion-exchange core particle. It is also noted that the claims do not require the polyelectrolyte copolymer material to interact with the ion-exchange core material in a particular fashion (e.g. via ionic interactions as described by Applicant at page 4). The claims also do not exclude coating the ion-exchange core particle by microencapsulation as described by Hennessy. Applicant appears to argue in the response that the word "coating" requires some sort of interaction other than microencapsulation (e.g. ionic bonding) (see page 4). However, this narrow definition of coating is not required by an explicit definition in the specification limiting the term as such. Moreover, the teachings of Hennessy provide support for interpreting microencapsulation as a type of coating. Specifically, in paragraph 25 of the reference, Hennessy explicitly describes the disclosed microencapsulation processes as a coating process. Finally, it is noted that the description of a coated particle in the instant application's specification (see pages 4-5) does not exclude methods, such as those of Hennessy, that include coating of the interior as well as the exterior of the ion-exchange core particle as argued by Applicant. Attention is directed to *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993), which states that, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Since the declaration filed under 37 CFR 1.131 and Applicant's arguments filed on September 30, 2009 are insufficient to overcome the Hennessy reference, the rejection of claims 21, 22, 24, 45, 46, 48, 49, 66-69, and 76-79 under 35 U.S.C. 102(a) and 35 U.S.C. 102(c) as being anticipated by Hennessy has been maintained

Regarding the rejections of claims 23, 47, 70-74, 80-84, 86, and 87 made under 35 U.S.C. 103(a) citing Hennessy as the primary reference, Applicant argues that the rejections should be withdrawn, since Hennessy does not qualify as prior art under 35 U.S.C. 102 in view of the declarations made under 37 CFR 1.131 and the arguments filed on September 30, 2009 (see pages 9-10). This argument was not persuasive, because as discussed above, the Hennessy reference still qualifies as a proper reference under 35 U.S.C. 102(a) and 102(e).

Regarding the provisional obviousness-type double patenting rejections made previously citing copending Applications 11/057,936 and 11/355,872, Applicant's response appears to indicate that terminal disclaimers have been filed for the '936 and '872 applications (see pages 10-11). It is noted that no terminal disclaimers are present in the electronic application file. Also, since the provisional obviousness-type double patenting rejections citing the later-filed '936 and '872 applications are not the only rejections remaining in the instant application, the rejections have been maintained in accordance with MPEP § 804.

Conclusion

12. No claims are currently allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Angela M Bertagna/
Examiner, Art Unit 1637

/GARY BENZION/
Supervisory Patent Examiner, Art Unit 1637